

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES



MMB Docket No. 1671-0278

J&J Reference: DEP5160USNP

Application of: Lester et al.

Group Art Unit: 3738

Serial No. 10/748,706

Examiner: Bruce Edward Snow

Filed: December 30, 2003

Title: Soft Tissue Attachment System and Method

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James D. Wood

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/James D. Wood/

Signature

December 19, 2006

Date of Signature

LETTER

Sir:

Enclosed is an Appeal Brief in connection with the above-identified patent application. The Notice of Appeal was filed on October 19, 2006, and the Appeal Brief was due two months from this date. Thus, this Appeal Brief is being timely filed on December 19, 2006. Also enclosed herewith is a check for \$500.00 to cover the fee required under 37 CFR 41.20(b)(2).

Additionally, please provide any extensions of time which may be necessary and charge any fees which may be due to Account No. 13-0014, but not to include any payment of issue fees.

Respectfully submitted,

MAGINOT, MOORE & BECK LLP

/James D. Wood/

December 19, 2006 Maginot, Moore & Beck LLP Chase Tower 111 Monument Circle, Suite 3250 Indianapolis, Indiana 46204-5109 (317) 638-2922 telephone (317) 638-2139 facsimile James D. Wood Attorney for Appellants Registration No. 43,285



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J&J Docket No. DEP 5160USNP

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Confirmation No.: 2131

Application of: Lester et al.

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December 19, 2006

Date of Signature

APPEAL BRIEF

Sir:

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This is an appeal under 37 CFR § 41.31 to the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office from the rejection of the claims 1-19 of the above-identified patent application. These claims were indicated as finally rejected in an Office Action dated July 19, 2006. The \$500.00 fee required under 37 CFR § 41.20(b) (2) is submitted herewith. Also, please provide any extensions of

time that may be necessary and charge any fees that may be due to Account No. 13-0014, but not to include any payment of issue fees.

(1) REAL PARTY IN INTEREST

DePuy Products, Inc. of Warsaw, Indiana is the assignee of this patent application, and the real party in interest.

(2) RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences related to this patent application (serial no. 10/748,706).

(3) STATUS OF CLAIMS

Claims 1-20 are pending in the application.

Claims 1-19 are rejected.

Claim 20 is objected to.

Claims 1-19 are being appealed, and are shown in the Appendix attached to this Appeal Brief.

(4) STATUS OF AMENDMENTS

Appellants have filed no amendments after receipt of the July 19, 2006, Office Action (the "Office Action").

(5) SUMMARY OF CLAIMED SUBJECT MATTER

The present invention relates to systems and methods for maintaining soft tissue attachment to bone in an orthopaedic procedure. (See, e.g. Appellants' specification at page 1, lines 6-8). In accordance with one non-limiting embodiment, a prosthesis 10 includes a body 11 that is configured to approximate the removed proximal portion P of a femur. (See, e.g. Appellants' specification at page 5, lines 4-8 and FIG. 3). The body 11 defines a neck 12 onto which a prosthetic articulating component of known design can be mounted. (See, e.g. Appellants' specification at page 5, lines 4-8 and FIG. 3). The prosthesis 10 also includes a stem 13 that is implanted within a bore B in a bone to fix the prosthesis 10 to the bone. (See, e.g. Appellants' specification at page 5, lines 4-8 and FIG. 3).

A mounting platform 15 on the body 11 defines surface features for mating engagement with a removed portion of the trochanter T. (See, e.g. Appellants' specification at page 5, lines 13-14 and FIGs. 4-5). As shown in FIGS. 4 and 5, the mounting platform defines a keystone slot 17 with a dovetail undercut 19 (best seen in FIG. 5). (See, e.g. Appellants' specification at page 5, lines 20-23 and FIGs. 4-5). The slot includes a mating surface 21 that is in direct contact with the bone portion T. (See, e.g. Appellants' specification at page 5, lines 20-23 and FIGs. 4-5). The bone portion T is cut to define a mating feature 25, as illustrated in FIGS. 6 and 7. (See, e.g. Appellants' specification at page 5, lines 23-25 and FIGs. 6-7). The mating feature includes a dovetail cut 27 at opposite sides of a mating surface 28. (See, e.g. Appellants' specification at page 5, lines 23-25 and FIGs. 6-7).

The additional information required by the United States Patent Office is as follows.

Claims 1-12

Claims 1-12 are argued together. Claim 1 is an independent claim. Claim 1 recites:

A method for repair of a joint comprising the steps of (see, e.g. Appellants' specification at page 2, lines 3-7):

removing a portion of a bone having natural soft tissue attached thereto (See, e.g. Appellants' specification at page 4, lines 25-26 and FIG. 2);

implanting an implant within the remaining bone leaving an exposed surface of the implant (See, e.g. Appellants' specification at page 5, lines 9-16 and FIG. 3);

preparing a surface of the removed portion of bone to provide the surface with a surface feature to mechanically interlock with a complementary feature defined on the exposed surface of the implant (See, e.g. Appellants' specification at page 5, lines 23-28 and FIGs. 6-7); and

mechanically engaging the surface feature of the removed portion of bone with the complementary feature of the implant when the implant is within the remaining bone while the natural soft tissue is still attached to the removed portion of bone (See, e.g. Appellants' specification at page 6, lines 4-9 and FIGs. 3, 5 and 7) such that the complementary feature of the implant does not extend completely through the removed portion of bone (See, e.g. Appellants' specification at page 6, lines 4-9 and FIGs. 3, 5 and 7).

Claims 13-16

Claims 13, 14 and 16 are argued together with respect to the rejection based upon Lee and claims 13-15 are argued together with respect to rejection based upon Caldarise.

Claim 13 is an independent claim. Claim 13 recites:

An implant for repair of a joint comprising (See, e.g. Appellants' specification at page 5, lines 9-16 and FIG. 3):

a stem configured for implantation within a bone of the joint (See, e.g. Appellants' specification at page 5, lines 9-16 and FIG. 3);

a head configured to replace a portion of the articulating aspect of the bone (See, e.g. Appellants' specification at page 5, lines 6-8 and FIG. 2); and

a body between said head and said stem (See, e.g. Appellants' specification at page 5, lines 6-8 and FIG. 3), said body including a surface defining a mechanical engagement feature configured to engage a complementary feature formed in a removed portion of the bone (See, e.g. Appellants' specification at page 5, lines 17-22 and FIGs. 3-4).

Claim 19

Claim 19 is argued separately. Claim 19 is an independent claim. Claim 19 recites:

A method of implanting a prosthesis comprising (See, e.g. Appellants' specification at page 5, lines 9-16 and FIG. 3):

resecting a portion of a bone having natural soft tissue attached thereto (See, e.g. Appellants' specification at page 4, lines 25-26 and FIG. 2);

implanting a prosthesis within the remaining bone (See, e.g. Appellants' specification at page 5, lines 9-16 and FIG. 3);

shaping the resected portion of bone to provide a bone tissue feature configured to mate with a feature of the implant (See, e.g. Appellants' specification at page 5, lines 23-28 and FIGs. 6-7); and

mating the bone tissue feature with the feature of the implant while the natural soft tissue is still attached to the resected portion of bone (See, e.g. Appellants' specification at page 6, lines 4-9 and FIGs. 3, 5 and 7).

(6) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1-12 stand rejected under 35 U.S.C. §112 as failing to comply with the written description requirement.

Claims 13-14, 16 and 19 stand rejected as being anticipated under 35 U.S.C. §102(b) by U.S. Patent No. 3,939,498 to Lee et al. (hereinafter "Lee").

Claims 13-15 stand rejected as being anticipated under 35 U.S.C. §102(b) by U.S. Patent No. 6,008,431 to Caldarise et al. (hereinafter "Caldarise").

Claims 17-18 stand rejected under 35 U.S.C. §103(a) as being obvious over Lee in view of U.S. Patent No. 5,163,961 to Harwin (hereinafter "Harwin") and/or U.S. Patent No. 4,889,110 to Galline et al. (hereinafter "Galline").

Claims 17-18 stand rejected under 35 U.S.C. §103(a) as being obvious over Caldarise in view of Harwin and/or Galline.

(7) ARGUMENT

Claims 1-12 Comply With 35 U.S.C. §112

Claims 1-12 stand rejected under 35 U.S.C. §112 for failing to comply with the written description requirement because of the phrase "the complementary feature of the implant does not extend completely through the removed portion of bone" which is found in claim 1. (Office Action at page 3). When the specification and the claims are properly construed, the claims are fully supported by the Appellants' specification.

1. The Examiner's Conclusion is Contrary to the Specification

In determining that the foregoing limitation was not described in the specification, the Examiner determined that the sentence "mating feature 25 cut into the bone portion T can extend along the entire cut surface C as represented by the dashed lines in FIG. 6" should be construed to mean that the mating feature 25 extends "completely through the removed portion of bone." (Office Action at page 3, citing to Appellants' specification at page 6). The Examiner has misconstrued the word "can."

Specifically, the Examiner has construed the word "can" to mean that the ensuing description is a necessary condition. While it may be possible to construct a sentence such that the word "can" should be interpreted to mean a necessary result, the usage of the word in the specification is not such a sentence, particularly when the figures are considered.

As an initial matter, the sentence associates the subject feature as being indicated by a "dashed" line, not a solid line. While dashed lines are used to identify hidden

features, and such hidden features are present in FIG. 6, dashed lines may also indicate optional constructions. Based solely upon the sentence, both interpretations may be possible. Referring to FIG. 6, the surface 25 is depicted with solid lines. Thus, the dashed lines extending from the upper surface of the surface 25 clearly indicate an *optional* feature, not a necessary one.

Accordingly, for the Examiner's position to be supported by the specification, the word "can" must be construed in such a manner as to not only identify a necessary feature, but also in a such a way that one of ordinary skill in the art would not be able to see the particular embodiment shown in FIG. 6. Any such interpretation is not reasonable.

Moreover, the Examiner's interpretation of the word "can" is directly contradictory to other portions of the Appellants' specification. FIG. 11 is described at page 8, lines 21-24 which states "[i]n the even (sic, event) that the dovetail cuts extend along the entire length of the bone portion, the slots 79 can be extended accordingly, as indicated by the dashed lines in FIG. 11." Thus, as depicted in FIG. 11, the cutting jig 70 is configured to allow for a dovetail that *does not* extend completely along the length of the removed portion of bone. Thus, even if "can" is to be interpreted in the manner suggested by the Examiner with respect to FIG. 6, FIG. 11 and its description expressly contradict the Examiner's conclusion.

Therefore, the Examiner has misconstrued the word "can" as used in the specification. When the word is construed in the context of the description of FIG. 6 and in the context of the discussion of FIG. 11, the word "can" should be construed to indicate a description of an optional feature. Therefore, the sentence "mating feature 25"

cut into the bone portion T can extend along the entire cut surface C as represented by the dashed lines in FIG. 6" should be construed to mean that the mating feature 25 may extend completely or merely partially along the bone portion. Additionally, FIG. 11 and its description provide express description of a mating feature 25 that extends only partially along the bone portion

Accordingly, because the Appellants' specification clearly discloses a mating feature which extends along a bone portion from one side to the other side as well as a mating feature that does not extend along a bone portion from one side to the other side, there is no support for the Examiner's rejection.

2. The Examiner has Misconstrued the Claim

Moreover, the limitation in claim 1 is directed to a feature of the *implant*, not the bone. Accordingly, while the feature 25 may be useful in understanding the nature of the complimentary feature of the *implant*, the proper analysis should focus on the keystone slot 17 of the mounting platform 15. As depicted in FIG. 5, the slot 17 includes undercuts 19 which are configured to abut the cut 27 (see FIG. 7) when the bone portion T is mounted on the mounting platform 15. Comparing FIG. 5 with FIG. 7 clearly reveals that the mating configuration is limited to the lower surface of the bone T. Therefore, the Appellants specification discloses an embodiment wherein "the complementary feature of the implant does not extend completely through the removed portion of bone."

3. The Examiner has Misconstrued the Word "Through"

Finally, the Examiner's argument as set forth above arrives at a conclusion as to the lack of teaching of an embodiment that does not extend completely *through* a bone portion based upon a disclosed feature that extends completely *along* one side of a bone portion. It is well established that the words of a claim must be given their plain meaning unless an applicant has provided a clear alternate definition in the specification. *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). Additionally, the claims are to be construed "in light of the specification as it would be interpreted by one of ordinary skill in the art." *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364, 70 USPQ2d 1827 (Fed. Cir. 2004). In view of the specification and the plain meaning of the claim terms, one of ordinary skill in the art would not construe "through a bone" to be the same as "along a bone."

Specifically, while both of the words "along" and "through" have a wide range of possible interpretations, some of which may overlap, in the context of the Appellants' specification, the words "through" and "along" have a distinct meaning to those of ordinary skill in the art. For example, the keystone slot 17 as shown in FIG. 4 is described as extending "along the entire length of the mounting platform 15."

(Appellants' specification at page 6, lines 10-11). As evidenced in FIG. 5, however, the undercuts 19 extend from a surface of the bone portion 11 downward into the bone portion 11, but do not extend *through* the bone portion 11 to the bottom of the bone portion 11. (See also Appellants' specification at page 6, lines 10 and 12, page 7 line 23 and page 8 line 22). Therefore, "along" describes a surface feature which extends beside a perimeter of an object.

In contrast, the word "through" is consistently used to describe a feature which extends from a perimeter into the center of the object and then back out via a different perimeter. For example, when describing the bone screws 52 shown in FIG. 9, the Appellants' specification states that "as shown in FIG. 9, the screws can be sized to penetrate only part way into the bone portion T. Alternatively, the screws can be sized to pass entirely through the bone portion and engage a corresponding screw bore (not shown) formed in the mounting platform 43 of the prosthesis body 41." (Appellants' specification at page 8, lines 2-5). (See also Appellants' specification at page 2, line 26, page 6, line 29, page 7, lines 2 and 28 and page 8 line 8). Therefore, "through" means a feature which penetrates a first side of an object, extends away from that side into the interior of the object and then extends out of another side of the object.

The foregoing constructions are consistent with the manner in which Lee uses the words. By way of example, in the Abstract, Lee identifies "a slot which extends longitudinally along the wider end of the stem." Further, Lee states the "slot being located along the outermost face [of the wider end]." (Lee at column 2, lines 13-15). Lee further describes a "shaft projecting from the device for passage through a bore." (Lee at Abstract). Therefore, Lee provides evidence that one of ordinary skill in the art would construe the term "along a bone portion" to mean a surface feature which extends beside the perimeter of the bone portion and that one of ordinary skill in the art would construe the term "through a bone portion" to mean a feature that penetrates a first side of a bone portion, extends inwardly away from the first side toward the interior of the bone portion and then extends out of another side of the bone portion.

Therefore, those of ordinary skill in the art, in light of the Appellants' specification, would not construe the word "through" to include a feature located only at the perimeter of the item. Consequently, a "complementary feature of the implant [that] does not extend completely through the removed portion of bone" is supported by the engagement of the undercuts 19 with the cut 27 since the undercuts 19, which engage the bone portion T at the bottom of the bone portion T as depicted in FIG. 7, do not penetrate a first side of bone portion T, extend inwardly away from the first side toward the interior of the bone portion T and then extend out of another side of the bone portion T. (Compare, e.g., FIG. 5 and FIG. 7).

4. Conclusion

Therefore, for any or all of the foregoing reasons, a "complementary feature of the implant [that] does not extend completely through the removed portion of bone" is described in the specification in such a way as to reasonably convey to one of ordinary skill in the art that at the time the Appellants' application was filed, that the Appellants were in possession of the claimed invention. Accordingly, the Board of Appeals is respectfully requested to overturn the rejection of claim 1.

Discussion re: Claims 2-12

Claims 2-12 were rejected on the same basis as claim 1. Accordingly, claims 2-12 comply with the written description requirement for at least the same reasons as those set forth above in connection with claim 1.

Claims 13-14 and 16 Are Not Anticipated by Lee

Claims 13-14 and 16 stand rejected under 35 U.S.C. §102(b) as being anticipated by Lee. (Office Action at page 5). Lee does not teach or disclose each element of the claims. Therefore, the rejections should be overturned.

Discussion re: Patentability of Claim 13

1. Claim 13

Claim 13 recites the following:

An implant for repair of a joint comprising:

- a stem configured for implantation within a bone of the joint;
- a head configured to replace a portion of the articulating aspect of the bone; and
- a body between said head and said stem, said body including a surface defining a mechanical engagement feature configured to engage a complementary feature formed in a removed portion of the bone.

Accordingly, claim 13 recites an implant body with a surface that defines a mechanical engagement feature that meshes with a feature formed in the bone.

2. Lee Has Been Mischaracterized

The Examiner has alleged that Lee discloses an implant body that meshes with a feature formed from bone. (Office Action at page 5). The Examiner has mischaracterized Lee.

Specifically, the Examiner has alleged that the bore 54 is a "surface feature" of the bone that mechanically interlocks with a "complementary feature" in the form of member 20 which is "defined on the exposed surface of the implant." (Office Action at page 5). The Examiner further states, with particular reference to claim 13, "stem 13, body 10, mechanical engagement feature 14 or 20. Note that the slot can be used to

accept a complementary feature formed in the trochanter. Said opening has "diverging opposing faces" which contain the enlarged portion 22." (Office Action at page 5).

The foregoing statements may be reasonably interpreted as an allegation that either 1) the bolt 20 is defined by the exposed surface of the body 10 and engages the bore 54, or 2) the member 20 is formed from the bone so as to fit within the slot of the body 10. The Appellants have previously addressed both of these interpretations.

In a previous response, the Appellants noted that Lee describes the member 20 as a bolt that is a component separate from the "main component 10." Therefore, it is not possible for a surface of the "main component 10" to "define" the bolt. The surface of the main component 10 may define a feature compatible with the bolt, e.g., the slot 14. The bolt, however, cannot fairly be said to be a part of the surface of the main component 10. Therefore, the first interpretation of the Examiner's rejection is not supported by Lee.

With respect to the second interpretation of the Examiner's rejection, the surface of Lee's prosthesis does define a slot. The slot 14, however, is not complementary to a feature formed in the removed bone tissue. The slot 14 only receives the bolt 20 with an enlarged head (Lee at column 2, lines 21-23 and 53-56) and a second bolt to keep the first bolt within the slot (Lee at column 2, lines 58-61). Thus, the slot of Lee is configured complementary to the head of a bolt, but not complementary to a surface feature of bone tissue. Moreover, as set forth at column 3, lines 5-8, Lee identifies the material used to make the member 20 as a "metal." Therefore, the member 20 is not formed from the bone.

Accordingly, the Examiner's rejection of claim 13, under either reasonable interpretation, rests upon a mischaracterization of Lee. Thus, Lee fails to disclose each and every element of claim 13. Accordingly, the Board of Appeals is respectfully requested to overturn the rejection of claim 13.

3. The Examiner's New Rejection

In response to the arguments previously presented by the Appellants, the Examiner stated that the "applicant argues that the bolt is a component separate from the main prosthesis which is not commensurate with the scope of the claim which fails to define "main" body. The rejection clearly states that the body includes a surface, such as a surface of the bolt, which is configured to engage a complementary feature formed in the removed bone." (Office Action at page 2). To the extent the Examiner's position can be understood, the Examiner has misconstrued the claim.

Specifically, while the "clearly stated" rejection does not appear in the Appellants' copy of the Office Action, and while the origin of the term "main body" is not known, the Examiner appears to be raising a new rejection based upon the premise that the word "body" in the claim is being broadly construed to mean any physical object. While it is not clear that such an allegation serves as a "rejection", the Appellants have responded herein out of an abundance of caution.

As stated by the Federal Circuit, "claims are not to be read in a vacuum, and limitations therein are to be interpreted in light of the specification in giving them their 'broadest <u>reasonable</u> interpretation'." *In re Marosi*, 710 F.2d 799, 802, 218 USPQ 289, 292 (Fed. Cir. 1983), quoting *In re Okuzawa*, 537 F.2d 545, 548, 190 USPQ 464, 466

(CCPA 1976)) (emphasis in original). Thus, the specification, including the claims, must be used in construing the claim terms.

Claim 17 depends from claim 13 and adds the limitation "at least one screw bore defined in said surface of said body." Claim 17 thus raises at least the inference that a "body" does not include a "screw." The other uses of the term "body" in the Appellants' specification confirm the meaning of the term. For example, at page 5, lines 4-5, the Appellants' specification states "the prosthesis 10 can include a body 11 that is configured to approximate the removed proximal portion P of the femur." (See also FIG. 1). At page 5, lines 6-7, the Appellants' specification states "[t]he body defines a neck 12 onto which a prosthetic articulating component of known design can be mounted." The Appellants' specification at page 5, lines 10-11 further notes that "[w]hile prior hip joint prostheses include a body that emulates the shape of the trochanter..." The term "body" is further used to describe an alternative embodiment wherein "a prosthesis body 31 can be provided with a keystone slot 33, configured as described above." (Appellants' Specification at page 6, lines 27-28.

Therefore, the term "body" is consistently used in the specification to identify the portion of a prosthesis positioned between the neck and the stem of the prosthesis. This is true both with respect to the disclosed embodiments of the invention as well as the description of the prior art. This usage is mimicked in the claim language which identifies the body as located "between said head and said stem."

Finally, this appears to be the construction initially adopted by the Examiner. For example, the Office Action discussion of claims 13-18 at page 5 states "stem 13, body 10, mechanical engagement feature 14 or 20." This appears to be a reference to Lee,

wherein the identified reference numerals are for the "stem 13" (Lee at column 2, line 2), the "component 10" (Lee at column 1, line 67), the "slot 14" (Lee at column 2, line 21) and the "member 20" (Lee at column 2, line 26). Thus, the Examiner indicated an understanding that the "body" limitation is directed generally to the same structure as the "component 10" of Lee.

The Examiner has failed to identify any valid basis for construing "body" in a manner contrary to the claims and the specification. Therefore, the Examiner's construction of claim 13 is unreasonable. Accordingly, the term "body" in claim 13, when properly construed, is not anticipated by a screw.

3. Conclusion

It is axiomatic that anticipation of a claim under 35 U.S.C. § 102 is proper only if the prior art reference discloses each and every element of the claim. Since Lee does not disclose an implant body with a surface that defines a mechanical engagement feature that meshes with a feature formed in the bone, Lee does not anticipate Appellants' claim 13. Accordingly, the Board of Appeals is respectfully requested to overturn the rejection of claim 13.

Discussion re: Patentability of Claims 14 and 16

Claims 14 and 16 depend from claim 13 and incorporate all the limitations of claim 13. Accordingly, claims 14 and 16 are patentable over the prior art for at least the same reasons as those set forth above in connection with claim 13.

Claim 19 Is Not Anticipated by Lee

Claim 19 stands rejected under 35 U.S.C. §102(b) as being anticipated by Lee. (Office Action at page 6). Lee does not teach or disclose each element of the claim. Therefore, the rejection should be overturned.

Discussion re: Patentability of Claim 19

1. Claim 19

Claim 19 recites the following:

A method of implanting a prosthesis comprising: resecting a portion of a bone having natural soft tissue attached thereto; implanting a prosthesis within the remaining bone;

shaping the resected portion of bone to provide a bone tissue feature configured to mate with a feature of the implant; and

mating the bone tissue feature with the feature of the implant while the natural soft tissue is still attached to the resected portion of bone.

Accordingly, claim 19 recites a method wherein an implant 1) is implanted into the portion of a bone remaining after another portion has been resected and 2) includes a structure that mates with a feature of a resected bone portion.

2. Claim 19 Has Been Misconstrued

The Examiner has alleged that Lee discloses the recited implanting step. (Office Action at page 5). The Examiner has misconstrued the claim.

Specifically, the Examiner alleges with respect to claim 19, that "the bore 53 was interpreted as the mating bone tissue feature which mates with "the feature of the implant" 20." (Office Action at page 2). Claim 19, however, further requires the implant to be implanted "within the remaining bone." The member 20 is arguably "implanted" within the bore 54 formed in the removed trochanter 53. The trochanter 53 is not,

however, the portion of a bone remaining after another portion has been resected. Rather, the trochanter 53 is the *removed* portion of the bone. Therefore, because the member 20 is not implanted "within the remaining bone" as recited in claim 19, the member 20 does not anticipate the step of "implanting" as recited in claim 19.

3. <u>Conclusion</u>

It is axiomatic that anticipation of a claim under 35 U.S.C. § 102 is proper only if the prior art reference discloses each and every element of the claim. Since Lee does not disclose an implant with a feature that mates with a bone and that is implanted into a remaining portion of bone as recited in Appellants' claim 19, Lee does not anticipate Appellants' claim 19. Accordingly, the Board of Appeals is respectfully requested to overturn the rejection of claim 19.

Claims 13-15 Are Not Anticipated by Caldarise

Claims 13-15 stand rejected under 35 U.S.C. §102(b) as being anticipated by Caldarise. (Office Action at page 6). Caldarise does not teach or disclose each element of the claims. Therefore, the rejections should be overturned.

Discussion re: Patentability of Claim 13

1. Claim 13

Claim 13 recites "a body between said head and said stem, said body including a surface defining a mechanical engagement feature configured to engage a complementary feature formed in a removed portion of the bone." Thus, a portion of the implant *other* than the stem must be configured to engage a removed portion of bone.

2. Caldarise Does Not Disclose a Body

The Examiner has maintained an anticipation rejection of claim 13. (Office Action at page 6). The Examiner has failed to identify each of the elements of claim 13 in the cited art.

Specifically, claim 13 recites "a body between said head and said stem." The only reference to a "body" in the Examiner's discussion of Caldarise is a reference to "said body including a surface 28..." (Office Action at page 6). The only two components the Examiner had previously identified in the discussion, however, were a "stem 25" and a "head." Thus, while it is not clear whether the Examiner intended to equate the "body" to the head or the stem, neither the head nor the stem can be "between said head and said stem" as recited in claim 13. Therefore, the Examiner has failed to identify each limitation of claim 13 in the cited art.

Anticipation under 35 U.S.C. § 102 is proper only if the prior art reference discloses each and every element of the claim. Accordingly, because claim 13 recites "a body between said head and said stem" and the Examiner has failed to allege that Caldarise discloses such an element, the Examiner has failed to properly allege anticipation.

3. The Stem of Caldarise is a Stem

In explaining the failure of Caldarise to anticipate the elements of claim 13, the Appellants previously noted that the recesses of Caldarise which the Examiner alleged to be the recited "mechanical engagement feature" were located on the *stem* of an implant,

not the *body*. (See Caldarise at column 3, lines 62-67 and Amendment dated May 8, 2006 at page 17). The Examiner has justified his reliance upon Caldarise arguing that "it is the Examiner's position that the noted mechanical engagement features are fully capable of fulfilling the functional language." (Office Action at page 3). Finding a similar function of a device in the prior art is not a proper basis for an anticipation rejection.

"The patentability of apparatus or composition claims depends on the claimed structure, not on the use or purpose of that structure." *Catalina Marketing International, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808, 62 USPQ2d 1781, 1785 (Fed. Cir. 2002) <u>citing In re Gardiner</u>, 171 F.2d 313, 315-16, 80 USPQ 99, 101 (CCPA 1948) ("It is trite to state that the patentability of apparatus claims must be shown in the structure claimed and not merely upon a use, function, or result thereof.").

Therefore, assuming *arguendo* that allowing for eventual ingrowth of a bone into the textured regions 28 of Caldarise constitutes "mechanical engagement," claim 13 still requires the mechanical engagement features to be located on a component "between said head and said stem." All of the textured regions 28 of Caldarise, however, are located on a lower portion 26 of a stem 25 which is "wedged securely into the femur and is eventually anchored there by new bone growth." (Caldarise at column 3, lines 60-67 and FIG. 1). A mechanical engagement feature located exclusively on the stem of an implant cannot also be located between the stem and the head.

Accordingly, because the textured regions 28 are not located between the stem and the head as recited in claim 13, Caldarise cannot anticipate claim 13.

4. Conclusion

Anticipation under 35 U.S.C. § 102 is proper only if the prior art reference discloses each and every element of the claim. Accordingly, because Caldarise does not disclose each element of claim 13 for any or all of the reasons set forth above, claim 13 is patentable over the prior art. Accordingly, the Board of Appeals is respectfully requested to reverse this rejection of claim 13.

Discussion re: Patentability of Claims 14-15

Claims 14-15 depend from claim 13 and incorporate all the limitations of claim 13. Accordingly, claims 14-15 are patentable over the prior art for at least the same reasons as those set forth above in connection with claim 13.

Claims 17-18 Are Not Obvious over Lee

The Examiner rejected claims 17 and 18 based primarily upon the same reasoning set forth above with respect to the anticipation rejection of claim 13 based upon Lee with further reference to Harwin and/or Galline for teaching the use of additional mechanical fixation. (Office Action at page 6). As discussed above, Lee does not disclose an implant body with a surface that defines a mechanical engagement feature that meshes with a feature formed in the bone as recited in claim 13. Accordingly, even if Lee is modified as proposed by the Examiner such modification does not correct the deficiencies of Lee as discussed above.

Under MPEP § 2142, the prior art must teach or suggest all of the claim limitations. Therefore, even assuming that Lee is modified to include additional mechanical fixation, a *prima facie* case of obviousness under 35 U.S.C. § 103 has not

been established with regard to the invention of claims 17-18 and the Board of Appeals is respectfully requested to reverse the rejections of claims 17-18.

Claims 17-18 Are Not Obvious over Caldarise

The Examiner rejected claims 17 and 18 based primarily upon the same reasoning set forth above with respect to the anticipation rejection of claim 13 based upon Caldarise with further reference to Harwin and/or Galline for the teaching of the use of additional mechanical fixation. (Office Action at page 7). As discussed above, Caldarise does not disclose a portion of the implant other than the stem configured to engage a removed portion of bone as recited in claim 13. Accordingly, even if Caldarise is modified as proposed by the Examiner such modification does not correct the deficiencies of Caldarise as discussed above.

Under MPEP § 2142, the prior art must teach or suggest all of the claim limitations. Therefore, even assuming that Caldarise is modified to include additional mechanical fixation, a *prima facie* case of obviousness under 35 U.S.C. § 103 has not been established with regard to the invention of claims 17-18 and the Board of Appeals is respectfully requested to reverse the rejections of claims 17-18.

(8) CONCLUSION

Claims 1-12 comply with the written description requirement of 35 U.S.C. §112. Additionally, claims 13-14, 16 and 19 are not anticipated by Lee, claims 13-15 are not anticipated by Caldarise and claims 17-18 are not obvious over either of Lee in view of

Harwin and/or Galline or Caldarise in view of Harwin and/or Galline. Accordingly, the Board of Appeals is respectfully requested to reverse the rejections of claims 1-19.

Respectfully submitted,

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(9) CLAIMS APPENDIX

Claim 1. A method for repair of a joint comprising the steps of:

implanting an implant within the remaining bone leaving an exposed surface of

removing a portion of a bone having natural soft tissue attached thereto;

the implant;

preparing a surface of the removed portion of bone to provide the surface with a surface feature to mechanically interlock with a complementary feature defined on the exposed surface of the implant; and

mechanically engaging the surface feature of the removed portion of bone with the complementary feature of the implant when the implant is within the remaining bone while the natural soft tissue is still attached to the removed portion of bone such that the complementary feature of the implant does not extend completely through the removed portion of bone.

Claim 2. The method for repair of a joint according to claim 1, wherein:

the complementary feature of the implant includes a female feature; and the step of preparing a surface includes defining a male surface feature on the removed portion of bone.

Claim 3. The method for repair of a joint according to claim 1, wherein the surface feature and the complementary feature define a dovetail joint.

Claim 4. The method for repair of a joint according to claim 1, wherein: the natural soft tissue is a ligament or a tendon; and

the surface feature and complementary feature are configured to maintain the ligament or tendon in tension when the removed portion of bone is mechanically engaged to the implant.

- Claim 5. The method for repair of a joint according to claim 4, wherein the surface feature and the complementary feature define opposing faces that diverge away from the intact attachment point of the ligament or tendon.
- Claim 6. The method for repair of a joint according to claim 5, wherein the surface feature and the complementary feature define a dovetail joint.
- Claim 7. The method for repair of a joint according to claim 1, further comprising the step of introducing bone cement between the removed portion of bone and the exposed surface implant.
- Claim 8. The method for repair of a joint according to claim 1, further comprising the step of providing the exposed surface of the implant with a surface configured to promote bone tissue ingrowth.

- Claim 9. The method for repair of a joint according to claim 1, wherein the joint is a hip joint, the removed portion of bone is the trochanter and the remaining bone is the remainder of the femur.
- Claim 10. The method for repair of a joint according to claim 1, further comprising the step of fixing the removed portion of bone to the implant using a mechanical fastener.
- Claim 11. The method for repair of a joint according to claim 10, wherein the mechanical fastener includes at least one screw configured to pass through the removed portion of bone and engage the implant.
- Claim 12. The method for repair of a joint according to claim 10, wherein the mechanical fastener includes at least one cerclage wire configured to encircle at least a portion of the removed portion of bone and engage the prosthesis.
- Claim 13. An implant for repair of a joint comprising:

a stem configured for implantation within a bone of the joint;

a head configured to replace a portion of the articulating aspect of the bone; and

a body between said head and said stem, said body including a surface defining a mechanical engagement feature configured to engage a complementary feature formed in a removed portion of the bone.

- Claim 14. The implant according to claim 13, wherein the mechanical engagement feature includes diverging opposing faces.
- Claim 15. The implant according to claim 13, wherein the mechanical engagement feature is the female portion of a dovetail joint.
- Claim 16. The implant according to claim 13, wherein at least a portion of said surface of said body is configured for bone tissue ingrowth.
- Claim 17. The implant according to claim 13, further comprising at least one screw and at least one screw bore defined in said surface of said body, said screw sized to pass through the removed portion of bone when the removed portion is engaged to said body.
- Claim 18. The implant according to claim 13, further comprising at least one cerclage cable engaged to said implant and configured to encircle a portion of the removed portion of bone when the removed portion of bone is engaged to said body.
- Claim 19. A method of implanting a prosthesis comprising:

 resecting a portion of a bone having natural soft tissue attached thereto;

 implanting a prosthesis within the remaining bone;

shaping the resected portion of bone to provide a bone tissue feature configured to mate with a feature of the implant; and

mating the bone tissue feature with the feature of the implant while the natural soft tissue is still attached to the resected portion of bone.

(10) EVIDENCE APPENDIX

None.

(11) RELATED PROCEEDINGS APPENDIX

None.